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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
Richard A. NAZARIAN et al.)	Group Art Unit: 2635
Application No.: 09/030,989)	Examiner: B. Zimmerman
Filed:	February 26, 1998)	Appeal No.
For:	ADAPTER POD FOR USE IN MEDICAL PERFUSION SYSTEM)	Confirmation No: 808 RECEIVED
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REQUEST FOR RECONSIDERATION OF APPEAL BRIEF AND SUPPLEMENTAL APPEAL BRIEF FOR APPELLANT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Date: September 24, 2003

Sir:

This Request for Reconsideration of the Appeal Brief and Supplemental Appeal is from the decision of the Primary Examiner dated April 28, 2003 (Paper No. 33), in which claims 16-38 were rejected. Claims 16-38 are reproduced in Appendix A. In addition, Figures 1-8, 12 and 17a-d are provided in Appendix B.

A check covering the [] \$160.00 (2402) [X] \$320.00 (1402) government fee was previously paid on February 5, 2003. Two extra copies of this brief are being filed herewith. Concurrently filed with this request is a Petition for Extension of Time for two months.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit-any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

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I. Real Party in Interest

The present application is assigned to Terumo Cardiovascular Systems Corporation, who is the real party in interest.

II. Related Appeals and Interferences

There are no currently known pending related appeals or interferences in the subject application.

III. Status of Claims

Claims 16-38 are pending and rejected.

IV. Status of Amendments

A Final Office Action was issued September 6, 2002 in which claims 16-22 were rejected and claims 23-38 were withdrawn from consideration. A Petition from the Request for Restriction was filed on January 29, 2003 and an Appeal Brief was filed on February 5, 2003 in response to the September 6, 2002 Office Action. A new Office Action dated April 28, 2003 was issued. This Request for Reconsideration of the Appeal and Supplemental Appeal Brief is filed in response to the April 28, 2003 Office Action.

V. Summary of the Invention

The invention is directed to an adapter pod for use in a medical perfusion system having a data communications network with a plurality of connection points each having a substantially identical network connector. The adapter pod includes a common connector adapted to be connected to one of the network connectors, a device connector adapted to be connected to a perfusion device, and means for generating a message in the form of a digital data packet. (page 2, lines 25-32)

As used herein, the term "perfusion device" is a device designed to be used in a medical perfusion system, including but not limited to a blood pump such as a centrifugal

or roller pump, a flow sensor, a pressure sensor, a temperature sensor, a level sensor, an air embolus sensor or an occluder. (page 5, lines 5-9)

Fig. 4 is a perspective view of the adapter pods 40 shown schematically in Fig. 1. Referring to Fig. 4, each adapter pod 40 has a hexahedral housing with one side 82 on which a connector 84 is disposed and an opposite side on which a connector 86 is disposed. The connector 86 is identical to the connectors 72 described above (and shown in Fig. 6) (page 5, line 34 through page 6, line 2)

The connector 84 is adapted to be connected to a device connector (not shown) that is associated with one of the perfusion devices 50 described above. The connector 84 has a different connector configuration than the connectors 60, 70, 72, 86. One example of the structure of the connector 84 is shown in Fig. 7 to include six conductive pins 88. Since each of the adapter pods 40 is adapted to be connected to a different type of perfusion device 50 (the pumps 50c, 50g may be different types of pumps, such as a roller pump or a centrifugal pump), the connector 84 disposed on each of the adapter pods 40 may have a different connector configuration. (page 6, line 3-13)

Since the connectors 60 of the main controller 20 and the connectors 70 of the network extenders 22 have the same connector configuration as the connector 86 of the adapter pods 40, it should be noted that any of the adapter pods 40 may be plugged into any of the connectors 60, 70. As a result, any combination of perfusion devices 50 may be connected to then main controller 20. (page 6, lines 14-20)

Fig. 8 illustrates the main controller 20 having the network extenders 22 and the adapter pods 40 connected to it. Each of the adapter pods 40 of Fig. 8 would be connected to a respective one of the perfusion devices 50 shown in Fig. 1 via a respective connector (not shown) attached to the perfusion device 50 by a cable. (page 6, lines 21-26)

Fig. 12 illustrates a block diagram of the adapter pod 40a shown schematically in Fig. 1. Referring to Fig. 12, the adapter pod 40a has a controller 180 which is powered by a power-supply-182-connected-to-the-electrical-power-lines_120a, 120b. The controller 180 may transmit a check-in code on the line 133 via a driver 184. The controller 180 receives

network messages from the data bus 152 and transmits messages onto the data bus 152 via a transceiver 186. (page 9, lines 5-12)

The controller 180 is connected to a memory 188 and to a device interface circuit 190. The device interface circuit 190 has a plurality of data lines 192 and a plurality of electrical power lines 194 which are connected to the perfusion device 50a via the connector 84 (Fig. 7). The controller 180 causes various types of data signals to be transmitted to the perfusion device 50a via the data lines 192. (page 9, lines 13-19)

Depending on the type of perfusion device 50 to which an adapter pod 40 is connected, the signals on the data lines 192 might include, for example, digital or analog signals (e.g. 4-20 ma signals) relating to the control of the perfusion device 50, such as a desired pump speed or mode of operation. The number of data lines 192 used depends on the particular perfusion device 50 to which the adapter pod 40 is connected. (page 9, lines 20-26)

The controller 180 also causes various types of electrical power to be transmitted to the perfusion device 50 via the power lines 194. These types of power include, for example, +5 volt DC power or +24 volt DC power. If power of another voltage level is necessary, the power supply circuit 182 may comprise a DC/DC converter. (page 9, lines 27-32)

The network controller 106 (Figs. 2 and 9) in the main controller 20, which may be a conventional network controller such as a CAN Version 2. 0B, oversees the data flow on the network buses 30, each of which includes the data bus 152 (which may be composed of two wires) on which digital data packets are transmitted and received. The data packets may have a conventional format composed of the following data fields: 1) a start-of-frame (SOF) field; 2) an arbitration field; 3) a control field; 4) a variable-length data field; 5) an error detection/correction field, such as a cyclic-redundancy-check (CRC) field; 6) an acknowledgment (ACK) field; and 7) an end-of-frame (EOF) field. (page 14, lines 16-27)

The arbitration-fields-contain a message identification (ID) code specifying the type of message, of a number of different data packet types that may be used. (page 14, lines 34-37)

The main controller 20, the extender controllers 32, and the adapter pods 40 may include conventional electronics for checking the accuracy of received messages via the CRC field, requesting retransmission of messages that were not accurately received, and for transmitting acknowledgment messages in response to the receipt of accurately received messages. (page 16, lines 16-21)

The messages described above may be transmitted or broadcast to all the devices connected to the network 30. Each device, such as a pod 40 or an extender controller 32, can discriminate by receiving only certain messages that are broadcast. For example, this discrimination could be accomplished by accessing a message-discrimination memory in the receiving device which stores the logical addresses of all other the devices in which the receiving device is interested. (page 16, lines 22-29)

For example, if the receiving device is the adapter pod 40c connected to the blood pump 50c which controls the flow of blood through a conduit based on receiving a feedback signal from the flow sensor 50a, the message-discrimination memory of the pod 40c would include the logical address of the flow sensor 50a, so that the pod 40c would receive any message generated by the pod 40a connected to the flow sensor 50a. (page 16, lines 30-36)

The message-discrimination memory would include logical address of the main controller 20, and could include the logical addresses of a number of other pods 40. Consequently, it should be noted that it is not necessary that messages broadcast over the network 30 include a specific destination address (although a destination address may be included). (page 17, lines 1-6)

Before use of the perfusion system 10 for a medical procedure, and after all the perfusion devices 50 are configured as described above, data packets containing

configuration messages are transmitted to all the pods 40 connected to the network 30. The configuration messages include all the necessary configuration data described above. For example, for a blood pump, the configuration data would include the operational mode of the pump, the desired flow rate of the pump, etc. If any configuration messages which include device association data (e.g. the sensor which a blood pump should receive feedback from) were received by a pod 40, the message-discrimination memory would be updated with the logical address of the associated device. (page 17, lines 14-26)

In order for them to communicate with the main controller 20 via the network data/power buses 30, the adapter pods 40 must be granted permission to connect to the network 30. This connection is initiated with a startup-request message transmitted to the main controller 20 by the adapter pod 40 for which the network connection is to be made. The startup-request message includes a first code identifying the type of perfusion device 50 connected to the pod 40 requesting to be connected and a second code identifying the physical address (specified by the code generator 144 of Fig. 11) of the pod 40 requesting to be connected. (page 17, line 21 through page 18, line 2)

During operation of the perfusion system 10, to ensure that all devices connected to the network 30 are properly functioning and are receiving messages broadcast over the network 30, the main controller 20 periodically transmits a status-request message to all extender controllers 32 and adapter pods 40 on the network 30. Each extender controller 32 and adapter pod 40 must respond to the status request within a predetermined period of time. Any extender controller 32 or pod 40 that fails to respond to the status request within that time period is disconnected from the network 30, and a corresponding alarm message is generated on the visual display 114 to warn the operator of such event. (page 20, lines 2-13)

The adapter pods 40 perform a number of functions, including receiving configuration and control messages transmitted by the main controller 20, receiving sensing messages containing numeric-values of sensed conditions, such as flow, and/or transmitting sensing messages over the network 30. These functions are described below. (page 27, lines 13-18)

Fig. 17A is a flowchart of a startup routine 520 performed by the controller 180 of each adapter pod 40. Referring to Fig. 17A, at step 522 the adapter pod 40 performs a number of internal self-tests, such as tests of an internal RAM and an internal ROM. At step 524, if the tests were successful, the program branches to step 526 where the connection of the pad 40 to the data bus 152 is tested by transmitting a message onto the data bus 152 and simultaneously receiving the message from the data bus 152 as it is transmitted to determine if the message was in fact transmitted. (page 27, lines 19-28)

At step 528, if the data bus test was successful, the program branches to step 530 where the adapter pod 40 starts to periodically transmit a check-in code to its parent node controller 34 via the line 133. At step 532, the pod 40 waits for its physical address to be transmitted to it from its parent node controller 34. At step 534, if not all of the tests performed at steps 522 and 526 were passed, an error message is broadcast over the network 30. The error message includes the physical address of the pod 40 and a binary code which specifies which test(s) were not passed. (page 27, line 29 through page 28, line 2)

If all tests were passed, the program branches to step 538 where a startup-request message containing the physical address of the adapter pod 40 is encoded and broadcast over the network 30. At step 540, the program waits until a startup-granted message is received from the main controller 20, and then at step 542 the program waits until full power is granted to the adapter pod 40 via the electrical power lines 120a, 120b of its parent node controller 34. When full power is granted, the program branches to step 544 where the pod 40 measures the voltages on and the current provided by the electrical power lines 120a, 120b to make sure they are within specification. At step 546, if the power measurements are not within specification, the program branches to step 536 where a message to that effect is broadcast to the main controller 20 over the network 30. (page 28, lines 3-17)

During-operation, an-adapter-pod-40-may-receive control or configuration messages from the main controller 20 over the network. Fig. 17B is a flowchart of a receive routine 550 that is performed when the adapter pod 40 receives a message. Referring to Fig. 17B,

at step 552 the message is decoded to determine the control command embedded in the message, and at step 554, the pod 40 transmits a control signal (via one or more of the data lines 192 in Fig. 12) to the perfusion device 50 connected to it. (page 28, lines 18-26)

During operation, an adapter pod 40 may receive an alarm signal from the perfusion device 50 via one of the data lines 192. When such an alarm signal is received, an alarm routine 560 shown in Fig. 17C is performed by the pod 40. Referring to Fig. 17C, at step 562 an alarm message is encoded with the logical address of the perfusion device 50 that generated the alarm and the type of alarm, and at step 564 the alarm message is broadcast over the network 30 to the main controller 20. (page 28, lines 27-34)

During operation, each adapter pod 40 connected to a perfusion device 50, such as a flow sensor, which generates a sensing signal periodically reads the numeric value of the sensing signal via one of the lines 152. The time period between successive readings of the sensing signal may be specified during the configuration process as described above. Fig. 17D is a flowchart of a sensing routine 570 that is performed when it is time to read the value of the sensing signal. Referring to Fig. 17D, at step 572 the sensing signal is read via one of the data lines 152. At step 574, the numeric value of the sensing signal is encoded in a message along with the logical address of the perfusion device 50 which generated the sensing signal. At step 576, that message is then broadcast over the network 30 to all devices connected to the network 30. (page 28, line 35 through page 29, line 12)

As described above, each adapter pod 40 connected to the network 30 may be provided with a message-discrimination circuit which is used to selectively receive messages from only a subset of the devices connected to the network 30. When the sensing message is broadcast at step 576, the only devices that receive it are the main controller 20 (which may receive all messages broadcast over the network 30) and the particular perfusion device 50 which is being controlled based on the value of the sensing signal encoded in the sensing message. (page 29, lines 13-21)

It-should-be-understood-that-the-adapter_pods_may_be_provided_with_additional functionality not described above. Also, instead of having electrical power being distributed over the network from a single power source provided in the main controller

20, electrical power could be distributed from a plurality of power sources, for example, from one power source provided in each of the network extenders. (page 29, line 22-28)

VI. The Issues

The issues presented for review are:

- 1) Whether claims 16-38 were properly rejected under 35 U.S.C. §103 as being unpatentable over *Dais et al.* (U.S. Patent No. 5,524,213), *Omori* (U.S. Patent No. 5,820,414), together or alternately in combination with *Schenk* (U.S. Patent No. 5,444,626) and Sites (U.S. Patent No. 5,730,720);
- 2) Whether claims 23 and 30 were properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,813,972; and
- 3) Whether claims 23-38 were properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-8 of U.S. Patent No. 5,813,972 in view of *Sites*.

VII. Grouping of Claims

Applicants respectfully submit that claims 17, 19-20, 22, 24-29 and 31-38 do not stand or fall together with claims 16, 18, 21, 23 and 30 as a group since these claims are separately patentable as discussed below.

VIII. Applicants arguments against the rejection of claims 16-38 under 35 U.S.C. §103

A. Errors in the Rejection

Applicants respectfully submit that the rejection of claims 16-38 is erroneous because the difference between the claimed subject matter and cited prior art is such that the invention would not have been obvious to a person of ordinary skill in the art at the time-the-invention-was-made. Applicants-respectfully-submit-that-the-Examiner is only selecting bits and pieces from those references without considering the remaining teachings of those references which would lead away from the claimed invention. Furthermore,

Applicants respectfully submit that the Examiner is misinterpreting *Dais et al.* and *Omori* and impermissibly modifying *Schenk* and *Sites* in light of Applicants teachings.

B. <u>Limitations Not Described in the Prior Art</u>

The limitations not described in the prior art are: a) an adaptor pod for use in a medical perfusion system as claimed in claims 16, 18, 21, 23 and 30; b) a controller or means for controlling electrical power to a perfusion device and for generating messages for the perfusion device and a main controller of the medical perfusion system as claimed in claims 16, 18 and 21; and c) a first connector coupled through a data bus to a communication network of a medical perfusion system, a second connector coupled to a perfusion device via a data line and a means for controlling or receiving a signal over the data line as claimed in claims 23 and 30.

C. Explanation of Why the Limitations Render the Claimed Subject Matter Unobvious over the Prior Art.

Dais et al. appears to disclose process control which takes place especially in motor vehicles, industrial robots, medical monitoring and analyzing apparatus, elevator systems and the like. In recent years, the data exchange for this process control between the individual opened-loop and closed-loop control units have taken place increasingly with the aid of methods for serial data exchange. Two classes of protocols have been formed including protocols having messages with short identifiers and protocols having messages with long identifiers. A method is therefore provided for operating a data-processing system as well as a method for structuring messages which is flexible with respect to the particular requirements. The method affords the advantage with respect to the state of the art that within one and the same bus system messages having identifiers of different lengths can be transmitted consistently and free of interaction with one and the same protocol. Figure 6 is a schematic of a data-processing system-for-use in a motor vehicle having several control apparatus operating at different locations and which are interconnected via a linear bus structure. The control apparatus are: an engine control unit 1, a transmission

control unit 2, an ABS-control unit 3, a steering control unit 4 and a climate control unit 5. Each of the control units has an interface component 8. A possible interface control unit 8 can, for example, be a CAN-controller which can carry out the data transmission according to the CAN-protocol. The interface component 8 must therefore be able to process message formats for long and short formats. Each interface component is connected to the bus line 7. A passive termination component 6 is disposed at the ends of the bus line 7 as a termination thereof. For data transmissions, that station which wishes to transmit data, sends a transmission request to the interface component 8 corresponding thereto. The interface component 8 which is addressed then carries out the transmission command independently and thereafter issues a transmission announcement to the station. The transmission announcement can contain the successful execution of the transmission command as well as possible error messages.

Thus, *Dias et al.* merely discloses a method for structuring messages which permits selection-free use of messages having both short or long identifiers in such a manner that these messages can be transmitted in any desired sequence over the same serial bus. Thus, *Dais et al.* is directed to any general network environment in which messages having both short and long identifiers can be transmitted over the same serial bus. Nowhere in *Dais et al.* is it shown, taught or suggested to have an adaptor pod for use in a medical perfusion system as claimed in claims 16, 18, 21, 23 and 30. *Dais et al.* at best merely discloses the process control which could take place within a medical monitoring system which permits the use of messages having both short and long identifiers and which can be transmitted in any desired sequence over the same serial bus. In other words, nothing in *Dais et al.* shows, teaches or suggests an adaptor pod and structure thereof used in a medical perfusion system as claimed in claims 16, 18, 21, 23 and 30.

Additionally, *Dais et al.* merely discloses interface components 8 having the structure of a CAN-controller such as shown in Figure 7. Thus nothing in *Dais et al.* shows, teaches or suggests a controller or means for controlling electrical power to a perfusion device or b) a controller or means for generating messages for a main controller and a perfusion device as claimed in claims 16, 18 and 21. Rather, *Dais et al.* merely

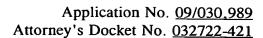
discloses the interface components 8 can be configured as a CAN-controller shown in Figure 7.

Also, Dais et al. merely discloses that the interface components 8 interface with one another. Thus nothing in Dais et al. shows, teaches or suggests a controller or means which generates messages for communication with a main controller of a medical perfusion system and a perfusion device as claimed in claims 16, 18 and 21. Rather, Dais et al. teaches away from the claimed invention and discloses that the interface components 8 interface with one another and not to a main controller.

Additionally, *Dais et al.* merely discloses a plurality of interface components 8 which can carry out data transmission between control units 1-5 and a bus line 7. Thus nothing in *Dais et al.* shows, teaches or suggests a) a common connector connected to an identical network connector of a data communication network of a medical perfusion system and b) a device connector connected to a perfusion device and having a connector configuration different from a connector configuration of the common connector as claimed in claims 16, 18 and 21. Rather, *Dais et al.* merely discloses a plurality of interface components 8 which connect between control units 1-5 and bus line 7.

Furthermore, *Dias et al.* merely discloses interface components 8 connected between control units 1-5 and bus line 7. Nothing in *Dias et al.* shows, teaches or suggests a first connector coupled through a data bus to any one of a number of connection points within a communication network that links perfusion devices, a second connector coupled to a blood pump or blood parameter sensing device via a data line and a means for controlling or receiving a signal over the data line to or from a medical profusion device as claimed in claims 23 and 30. Rather, *Dias et al.* merely discloses interface components 8 connected between control units 1-5 and bus line 7.

Finally, *Dias et al.* merely discloses control units 1-5. Nothing in *Dias et al.* shows, teaches or suggests a controller which selectively supplies power to a device interface-circuit-as-claimed-in-claim-20-or-a device-connector-having-a-first-number-of-signal lines and a common connector having a different number of signal lines as claimed in claims 17, 19 and 22. Furthermore, *Dias et al.* does not show, teach or suggest that the



control signal defines a desired pump speed for a blood pump as claimed in claim 24 or a mode of operation for a blood pump or blood parameter sensing device as claimed in claims 25 and 38. Also, *Dias et al.* does not show, teach or suggest a centrifugal pump or roller pump claimed in claims 26, 27, a means for processing an alarm signal via a data line as claimed in claim 28, encoding means for encoding an alarm message and broadcast means for broadcasting the alarm message as claimed in claim 29, a reading means for reading a numerical value representing a blood parameter claimed in claim 31, encoding means for encoding a message that identifies the numeric value and broadcasting means for broadcasting a message as claimed in claim 32, that the message identifies a numeric value representing blood flow, blood pressure, blood temperature, blood flow occlusion or an air embolus as claimed in claims 33-37.

Omori appears to disclose an IC card adapter including a main connector to . . . provided on a side of a body while a plurality of sub-connectors 3A, 3B are provided on ... the reverse side. The main-connector 2 is for obtaining an electrical connection with an equipment (e.g. a personal computer) in which the IC card 1 is used. On the other hand, sub-connectors 3A, 3B are for obtaining electrical connection with adapters. The IC card 1 includes a frame pod made of plastic which forms an outer shape of a card body, and an electrical circuit board 6 in which prescribed electronic components 7 included semiconductor circuits are incorporated, and, a main-connector 2 and the sub-connectors 3A, 3B are mounted at a front end portion and a rear end portion of the electric circuit board 6 respectively. A IC card adapter 11 to be used by connecting to the IC card 1 includes a plurality of adapter-side main-connectors 12A, 12B (primary connectors) to be respectively coupled with the sub-connectors 3A, 3B of an IC card 1 and are provided on a side of the adapter 11. On the other hand, one or a plurality of adapter-side sub-connectors 13 are provided on the reverse side. To this adapter-side sub-connector 13, a connector 19 with a cable is connected, and at another end of the cable 19A of the connector 19, for example-a-connector-(not-shown)-to-be-connected-electrically_to-a_telephone_circuit_is_ provided. The IC card adapter 11 includes a frame 15, and an electric circuit board 16 in which prescribed electronic components 17 are incorporated. The electric circuit board 16

mounted with the electronic components form an adapter module 18 which has a telephone function including a speaker function and a microphone function which is different from the function which the IC card 1 has possessed primarily.

Thus, *Omori* merely discloses a IC card adapter having a telephone function to be connected with a IC card which has a different function. Nothing in *Omori* shows, teaches or suggests an adapter pod for use in a medical perfusion system as claimed in claim 16, 18 21, 23 and 30. Rather, *Omori* merely discloses a IC card adapter having a telephone function which allows expansion or improvement of the functions of an IC card.

Additionally, *Omori* merely discloses that the IC card adapter 11 includes electronic components 17 which have a telephone function different from the function of an IC card 1. Nothing in *Omori* shows, teaches or suggests a controller or means for generating messages for communication with a perfusion device and a main controller of a medical perfusion system as claimed in claims 16, 18 and 21. Rather, *Omori* merely discloses electronic components 17 and an adapter 18 having a telephone function different from the functions of the IC card 1.

Also, *Omori* discloses at column 7 lines 38-48 that the adapter module 18 is driven by electric power supplied from a personal computer through a IC card 1. Thus nothing in *Omori* shows, teaches or suggests a controller or means which controls electrical power to a perfusion device as claimed in claims 16, 18 and 21. Rather, *Omori* merely discloses that electrical power is supplied to the adapter module 18 from a personal computer through the IC card 1.

Furthermore, *Omori* merely discloses a IC card adapter 11 having connectors 12a, 12b for connection to IC card 1 and having a connector 13 for connection to a connector 19 with a cable 19a to a public circuit. Nothing in *Omori* shows, teaches or suggests a first connector coupled through a data bus to a communications network which links each of a plurality of profusion devices in a medical profusion system and a second connector coupled to a blood pump or a blood parameter sensing device via a data-line as claimed in claims 23 and 30. Rather, *Omori* merely discloses a IC card adapter 11 connected to a IC card 1 and to a connector 19 of a cable 19a of a public circuit.

Additionally, nothing in *Omori* shows, teaches or suggests means for controlling or receiving a signal over a data line to a blood pump or from a blood parameter sensing device as claimed in claims 23 and 30. Rather, *Omori* merely discloses a IC card adapter having a telephone function.

Finally, *Omori* merely discloses supplying the adaptor module 18 with electrical power through the IC card 1. Nothing in *Omori* shows, teaches or suggests a) a controller which selectively supplies power to a device interface circuit as claimed in claim 20 or b) different number of signal line for connectors as claimed in claims 17, 19 and 22. Furthermore, Omori does not show, teach or suggest that the control signal defines a desired pump speed for a blood pump as claimed in claim 24 or a mode of operation for a blood pump or blood parameter sensing device as claimed in claims 25 and 38. Also, Omori does not show, teach or suggest a centrifugal pump or roller pump claimed in claims 26, 27, a means for processing an alarm signal via a data line as claimed in claim 28, encoding means for encoding an alarm message and broadcast means for broadcasting the alarm message as claimed in claim 29, a reading means for reading a numerical value representing a blood parameter claimed in claim 31, encoding means for encoding a message that identifies the numeric value and broadcasting means for broadcasting a message as claimed in claim 32, that the message identifies a numeric value representing blood flow, blood pressure, blood temperature, blood flow occlusion or an air embolus as claimed in claims 33-37.

Schenk appears to disclose a control system for a motor vehicle in which overloading of the serial bus is avoided by not transmitting, on a bus, operating values which are inappropriate to the current operating mode for the vehicle. The control system includes a central processing unit 20, an ignition module 21, a fuel injection module 22 and a brake module 23. The components are connected to an external data bus 24. For connection to the external data bus 24 each component is provided with an interface 25. In addition to the interface 25, the central-processing-unit-20-is-provided-with-a microprocessor 20a and a memory component 20b. In addition to their interfaces 25, each of the depicted modules 21, 22 and 23 is also provided with a microprocessor as well as a

memory component and input and output circuits. For calculating the respective parameter control values, transducer signals from individual control modules 21, 22 and 23 must be fed to the central processing unit 20. For that reason, the modules are continually transmitting these values to the central processing unit 20 by way of the external data bus 24.

Thus, *Schenk* merely discloses a control system for motor vehicles which prohibits transmission of parameters which are not appropriate for the current operating mode of the vehicle. Nothing in *Schenk* shows, teaches or suggests and adapter pod for use in a medical perfusion system as claimed in claims 16, 18, 21, 23 and 30. Rather, *Schenk* is merely directed to a control system for a motor vehicle which prohibits transmission of certain parameter values based upon the operating mode of the vehicle.

Additionally, *Schenk* merely discloses a central processing unit 20, an ignition module 21, a fuel injection module 22, a brake module 23, an external data bus 24 and an interface 25 provided in each component to connect to the external data bus 24. Nothing in *Schenk* shows, teaches or suggests a controller or means which controls electrical power to a perfusion device as claimed in claims 16, 18 and 21. Rather, *Schenk* merely discloses an interface module 25 provided in each module 20-23 for communication with an external data bus 24.

Also, *Schenk* merely discloses interface 25 for interconnection with the external data bus 24. Nothing in *Schenk* shows, teaches or suggests a controller or module for generating messages for communication with a perfusion device and a main controller of a medical perfusion system as claimed in claims 16, 18 and 21. Rather, *Schenk* merely discloses an interface 25 for communication with the external data bus 24.

Furthermore, *Schenk* merely discloses a central electronic control unit for a motor vehicle for exchanging data through a serial data bus with other control units. Nothing in *Schenk* shows, teaches or suggests a means for controlling the transmission of a blood pump control signal from an adapter pod to a blood pump over a data-line as elaimed in claim 23 or a means for receiving a blood parameter signal from a blood parameter sensing device over a data line as claimed in claim 30. Rather, *Schenk* merely discloses a central

electronic unit in a motor vehicle to exchange data through a serial data bus with other control units.

Additionally, *Schenk* merely discloses an interface 25 for control units 21-23 connected to an external data bus 24. Nothing in *Schenk* shows, teaches or suggests a first connector connecting to a communication network that links a plurality of profusion devices and a second connector coupling a blood pump or blood parameter sensing device via a data line as claimed in claims 23 and 30. Rather, *Schenk* merely discloses interface 25 connecting control units 21-23 to an external data bus 24.

Finally, *Schenk* merely discloses central processing unit 20 and modules 21-23. Nothing in *Schenk* shows, teaches or suggests a) a controller which selectively supplies power to different number of signal lines for connectors as claimed in claims 17, 19 and 22. Furthermore, *Schenk* does not show, teach or suggest that the control signal defines a desired pump speed for a blood pump as claimed in claim 24 or a mode of operation for a blood pump or blood parameter sensing device as claimed in claims 25 and 38. Also, *Schenk* does not show, teach or suggest a centrifugal pump or roller pump claimed in claims 26, 27, a means for processing an alarm signal via a data line as claimed in claim 28, encoding means for encoding an alarm message and broadcast means for broadcasting the alarm message as claimed in claim 29, a reading means for reading a numerical value representing a blood parameter claimed in claim 31, encoding means for broadcasting a message that identifies the numeric value and broadcasting means for broadcasting a message as claimed in claim 32, that the message identifies a numeric value representing blood flow, blood pressure, blood temperature, blood flow occlusion or an air embolus as claimed in claims 33-37.

Sites et al. appears to disclose automatically controlling temperatures and rates of change of temperature in the subject of a perfusion hyperthermia or hypothermia treatment using a programmed computer system. (col. 1, lines 8-11) In one embodiment, an apparatus and method are provided for using a computerized system-for-a-perfusion—hyper/hypothermia treatment of a patient which obtains a body fluid having a particular temperature. A plurality of temperature signals representative of temperatures at each of a

plurality of patient locations on or within the patient are coupled to the computer system. Measured temperatures are compared to a set of stored parameters in the computer system to generate a comparison value which controls a change in the temperature of the body fluid which is made by the extracorporeal fluid-treatment system. The body fluid is then perfused into the patient to either warm, cool, or maintain the current temperature of the patient. (col. 2, lines 25-37) FIG. 1 shows a conceptual drawing of one embodiment of a perfusion hyper/hypothermia treatment system (PHTS) 100 comprising computer system 110 for monitoring and controlling the system using input from a user, monitoring system 200 for measuring various parameters of the PHTS 100 and patient 99 (or other biological organism, organ, or preparation being treated, hereinafter collectively called "patient 99") and for providing representative signals to computer system 110, perfusion system 400 for withdrawing blood from patient 99 and later returning the blood after treatment, and extracorporeal circuit (ECC) 300 for treating the withdrawn blood. PHTS 100 can be used to effect either hyperthermia or hypothermia of patient 99, depending on the treatment desired. (col. 5, line 64 through col. 6, line 10) In one such embodiment, output device 160 also comprises an audio output device 162, such as an electronically-driven buzzer or speaker, used to alert the user of various exigencies or other conditions. In one such embodiment, audio-output device 162 comprises a tone generator producing different sounds for alerting a user to various warnings or alarms. In another such embodiment, recorded or synthesized voice signals are converted to sound by audio-output device 162, for alerting a user to various warnings or alarms. (col. 7, lines 27-36) FIG. 3 shows a schematic of a portion of electrical subsystem 700 including sensor and control connections and configuration for one embodiment of ECC 300, monitoring system 200 and computer system 110. (col. 11, lines 31-34) The sensor probes of ECC 300 include probes 315 and 316 at the blood input and output points, respectively, to blood preconditioner 310, probes 325 and 326 at the blood input and output points, respectively, to blood pump 320, probes 335-and-336-at-the-blood-input-and-output-points, respectively, to heat exchanger 330, ____ probes 345 and 346 at the water input and output points, respectively, to waterconditioning subsystem 340, and probes 385 and 386 at the blood input and output points,

respectively, to blood postconditioner 380. The sensor probes of ECC 300 include, for example, devices for measuring the pressure in the blood circuit, the speed of and/or blood-flow rate through blood pump 320, the temperature gain of blood through heat exchanger 330, the fluid level of water reservoir 343, the temperature of the water exiting water heater 350, the speed of water pump 370, and whether there are bubbles in the blood circuit. (col. 11, line 66 through col. 12, line 15)

Thus, Sites et al. merely discloses a computerized system for a perfusion hypothermia treatment. Nothing in Sites et al. shows, teaches or suggests an adapter pod for use in a medical perfusion system as claimed in claim 16, 18, 21, 23 and 30. Rather, Sites et al. is merely directed to the medical perfusion system itself. Sites et al. does not show, teach or suggest an adapter pod.

Additionally, Sites et al. merely discloses a treatment system 100 comprising a computer system 110 for monitoring and controlling the system, a monitoring system 200 for measuring various parameters, a perfusion system 400 for withdrawing and returning blood to a patient and a circuit 300 for treating the withdrawn blood. Nowhere in Sites et al. is it shown, taught or suggested that an adaptor pod comprises a common connector connected to an identical network connector of a data communication network, and a device connector having a connector configuration different from the common connector as claimed in claims 16, 18 and 21. Rather, the exact connectors to connect the system together are not shown, taught or suggested in Sites et al.

Furthermore, since *Sites et al.* does not show, teach or suggest an adaptor pod, nothing in *Sites et al.* shows, teaches or suggests a controller or means which generates messages for communication with a main controller of a medical perfusion system and a perfusion device as claimed in claim 16, 18 and 21. No adapter pod is shown, taught or suggested by *Sites et al.* and thus no controller or means therefore is shown, taught or suggested.

Also, Sites et al. merely discloses probes 315, 316, 335, 336, 325, 326 and 385, 386. Nothing in Sites et al. shows, teaches or suggests an adapter pod comprising a first connector coupling to a communication network linking a plurality of perfusion devices and

a second connector coupling a blood pump via a data line or a blood parameter sensing device via a data line as claimed in claims 23, 30. Rather, *Sites et al.* merely discloses probes connecting a blood preconditioner 11, blood pump 320, heat exchanger 330 and blood post-conditioner 380 to a multiplexer 121 of a computer system 110.

In addition, *Sites et al.* merely discloses an interface circuit 120 connected to a computer 111 of a computer system 110. Nothing in *Sites et al.* shows, teaches or suggests an adapter pod comprising a means for controlling transmission of a blood pump control signal to a blood pump over a data line as claimed in claim 23 or a means for receiving a blood parameter signal from a blood parameter sensing device over a data line as claimed in claim 30. Rather, *Sites et al.* merely discloses a plurality of probes sending signals from various devices to an interface circuit 120 of a computer system 110.

Finally, *Sites et al.* merely discloses a perfusion system but does not show, teach or suggest a) a controller of an adapter pod which selectively supplies power to a device interface circuit as claimed in claim 20, b) a different number of signal lines for connecters as claimed in claims 17, 19 and 22. Furthermore, *Sites et al.* does not show, teach or suggest that the control signal defines a desired pump speed for a blood pump as claimed in claim 24 or a mode of operation for a blood pump or blood parameter sensing device as claimed in claims 25 and 38. Also, *Sites et al.* does not show, teach or suggest a centrifugal pump or roller pump claimed in claims 26, 27, a means for processing an alarm signal via a data line as claimed in claim 28, encoding means for encoding an alarm message and broadcast means for broadcasting the alarm message as claimed in claim 29, a reading means for reading a numerical value representing a blood parameter claimed in claim 31, encoding means for encoding a message that identifies the numeric value and broadcasting means for broadcasting a message as claimed in claim 32, that the message identifies a numeric value representing blood flow, blood pressure, blood temperature, blood flow occlusion or an air embolus as claimed in claims 33-37.

D. Why the References Taken as a Whole Do Not Suggest the Claimed
Invention and Why the Features Disclosed in One Reference May Not Be
Properly Combined with the Features Disclosed in the Other Reference.

Applicants respectfully point out that the claimed invention is directed to an adapter pod for use in a medical perfusion system. In particular, due to the structure of the adapter pod, a medical perfusion system will be configurable so that it can be used for many different purposes. Dais et al. on the other hand is merely directed to using different message lengths on a serial bus. Nowhere in Dais et al. is it shown, taught or suggested to have an adapter pod for use in a medical perfusion system and in particular to an adapter pod having a) a controller or means which controls electrical power to a perfusion device and which generates messages for the perfusion device and a main controller of the medical perfusion system or b) a first connector coupled through a data bus to a communication network of a medical perfusion system, a second connector coupled to a perfusion device via a data line and a means for controlling or receiving a signal over the data line.

Omori as discussed above is merely directed to attaching an adapter IC module in order to improve a IC card and in particular an adapter module having a different telephone function than an IC card. Nowhere in *Omori* is it shown, taught or suggested to have an adapter pod for use in a medical perfusion system and in particular an adaptor pod having a) a controller or means for controlling electrical power to the perfusion device and for generating messages for communication of the perfusion device and a main controller of the medical perfusion system or b) a first connector coupled through a data bus to a communication network of a medical perfusion system, a second connector coupled to a perfusion device via a data line and a means for controlling or receiving a signal over the data line.

Schenk, as discussed above, merely discloses a control system for a motor vehicle which prohibits transmission of certain parameters during different operation modes of the vehicle. Nowhere in Schenk is it shown, taught or suggested to have an adapter pod for use in a medical perfusion system and in particular an adaptor pod having a) a controller or means for controlling electrical power to the perfusion system and for generating messages

for communication of the perfusion device and the main controller of the medical perfusion system or b) a first connector coupled through a data bus to a communication network of a medical perfusion system, a second connector coupled to a perfusion device via a data line and a means for controlling or receiving a signal over the data line.

Sites et al. as discussed above is merely directed to a computerized system for a perfusion treatment device. Nowhere in Sites et al. is it shown, taught or suggested to have an adapter pod and in particularly to an adapter pod having a) a controller or means for controlling electric power to the perfusion system and for generating messages for communication of the perfusion system and the main controller or b) a first connector coupled through a data bus to a communication network of a medical perfusion system, a second connector coupled to a perfusion device via a data line and a means for controlling or receiving a signal over the data line.

Applicants respectfully submit that Dais et al., Omori, Schenk and Sites et al. can not be combined as suggested by the Examiner. Dais et al., Omori and Schenk have anything to do with a medical perfusion system or more specifically, adapter pods for use in a medical perfusion system. Sites et al. discloses a perfusion system but does not show, teach or suggest an adaptor pod and structure thereof. Dais et al. at best discloses that the device can be used in medical monitoring and analyzing apparatuses. However, nowhere in Dais et al. is it expressly or implicitly suggested that it is applicable to a medical perfusion system or to adapter pods for use in medical perfusion systems. *Omori* merely describes a IC card adapter for use in "computer devices" such as personal computers. Schenk on the other hand merely describes a system which derives control values for motor vehicle control processes and does not describe in any way an adapter pod for use in a medical perfusion system. Thus none of Dais et al., Omori, Schenk, or Sites et al. taken singularly or in combination show, teach or suggest a) a medical perfusion system, b) an adapter pod for use in a medical perfusion system, c) a means or controller for controlling electrical-power-to-a-perfusion-device-and-for-generating-messages-for-the-perfusion-device and the main controller of the medical perfusion system or d) first and second connectors and means for controlling and receiving a signal.

Applying Site et al. to Dais et al., Omori and Schenk would still not teach an adapter pod as claimed. Thus, even if the references were combined as suggested by the Examiner, the combination of the references would merely suggest that the perfusion system Sites et al. would a) send messages of different lengths for exchanging of data as taught by Dias et al., b) be attached to an IC card adapter and to an IC card to have a telephone function different from the function of the IC card as taught by Omori while c) prohibiting transmission of certain parameters during inappropriate operation periods as taught by Schenk. Thus, nothing in the combination of the references as suggested by the Examiner shows, teaches or suggests the invention as claimed in claims 16, 18, 21, 23 and 30. Furthermore, none of the references shows, teaches or suggests the additional features as discussed above for claims 17, 19, 20, 22, 24-29 and 31-38.

For all of the above stated reasons, Applicants respectfully request that the Honorable Board of Patent Appeals and Interferences reverses the Examiner's rejection of claims 16-38 under 35 U.S.C. §103.

IX. Applicants' Arguments Against the Rejection of Claims 23 and 30 Under the

Judicially Created Doctrine of Obviousness-Type Double Patenting

A. Errors in the Rejection

Applicants respectfully submit that the rejection of claims 23 and 30 is erroneous under the judicially created doctrine of obviousness-type double patenting based upon MPEP 804.01 and 804.02.

B. Specific Reasons Why the Rejection is in Error

Applicants respectfully point out that this application is a continuation of U.S. Application Serial No. 08/723,504 filed September 30, 1996 which is now U.S. Patent No. 5,813,972.—Applicants-additionally-point-out-that-in-the parent-application, U.S. Patent No. 5,813,972, in an Office Action dated September 16, 1997, paper number 7, a restriction requirement was issued in which Applicants were required to elect between

claims 1-15 directed to a medical perfusion device or claims 16-17 directed to an adapter pod. It is respectfully submitted that the restriction by the Examiner in the parent application prevents claims 16-38 from being rejected under the judicially created doctrine of double patenting. Furthermore, Applicants respectfully point out that a terminal disclaimer was filed on July 8, 2002.

For all of the above stated reasons, Applicants respectfully request the Board of Patent Appeals withdraws the rejection to claims 23 and 30 under the judicially created doctrine of obviousness-type double patenting.

X. Applicants' Arguments Against the Rejection of Claims 23-38 Under the Judicially
Created Doctrine of Obviousness-Double Patenting

A. Errors in the Rejection

Applicants respectfully submit that the rejection of claims 23-38 under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 5,813,972 in view of *Sites et al.* is erroneous based upon MPEP 804.

B. Specific Reasons Why the Rejection is in Error

Applicants respectfully submit that the rejection of the claims is in error since the double patenting rejection must rely on a comparison with the <u>claims</u> in the issued patent. Applicants respectfully point out that claims 1 and 6-8 of parent application U.S. Patent No. 5,813,972 are directed to a medical perfusion system and <u>not</u> to an adapter pod as claimed in claims 23-38. Therefore, Applicants respectfully submit that the rejection is in error.

For all of the above stated reasons, Applicants respectfully request the Honorable Board of Patent Appeals and Interferences reverses the Examiner's rejection of claims 23-38-under-the-judicially-created-doctrine-of-obviousness-type-double-patenting.

XI. Conclusion

For all of the above stated reasons, Applicants respectfully request the Honorable Board of Patent Appeals and Interferences reverses the Examiner's decision in this case since Applicants respectfully submit that the final rejection of claims 16-38 is an error. Therefore, Applicants respectfully submit that claims 16-38 should be allowed.

In the event that this paper is not timely filed within the currently set short and statutory period, Applicants respectfully petition for an appropriate extension of time, the fees for such an extension of time may be charged to our deposit account number 02-4800.

In the event that any additional fees are due with this paper, please charge deposit account number 02-4800.

Respectfully submitted,

BURNS, DOANE SWECKER & MATHIS, L.L.P.

By:

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Date: September 24, 2003

APPENDIX A

The Appealed Claims

16. An adapter pod for use in a medical perfusion system, said medical perfusion system having a main controller and a data communications network with a plurality of connection points, each connection point having a substantially identical network connector, said adapter pod comprising:

a common connector adapted to be connected to one of said identical network connectors, said common connector having a connector configuration;

a device connector adapted to be connected to a perfusion device, said device connector having a connector configuration different than said connector configuration of said common connector; and

means for controlling electrical power to said perfusion device and for generating messages, in the form of a digital data packet, for said main controller and said perfusion device.

- 17. An adapter pod as defined in claim 16 wherein said device connector has a first number of signal lines and wherein said common connector has a second number of signal lines different than said first number.
- 18. An adapter pod for use in a medical perfusion system, said medical perfusion system having a main controller and a data communications network with a plurality of connection points, each connection point having a substantially identical network connector, said adapter pod comprising:

a housing;

a common connector associated with said housing, said common connector adapted to be connected to one of said identical network connectors and having a connector configuration;

a device connector associated with said housing, said device connector being adapted to be connected to a perfusion device and having a connector configuration different than said connector configuration of said common connector; and

a controller disposed within said housing, said controller controls electrical power to said perfusion device and being adapted to generate messages, in the form of digital data packets, for communication with said main controller and said perfusion device.

- 19. An adapter pod as defined in claim 18 wherein said device connector has a first number of signal lines and wherein said common connector has a second number of signal lines different than said first number.
 - 20. An adapter pod as defined in claim 18 additionally comprising:
 - a device interface circuit; and
 - a power supply circuit,

wherein said controller is coupled to control said power supply circuit to selectively supply power to said device interface circuit.

- 21. An adapter pod for use in a medical perfusion system, said medical perfusion system having a main controller and a data communications network with a plurality of connection points, each connection point having a substantially identical network connector, said adapter pod comprising:
 - a housing;
- a common connector associated with said housing, said common connector adapted to be connected to one of said identical network connectors and having a connector configuration;
- a device connector associated with said housing, said device connector being adapted to be connected to a perfusion device and having a connector configuration different than said connector configuration of said common connector;
 - a power supply circuit; and
- a controller disposed within said housing, said controller being adapted to generate messages, in the form of digital data packets, for communication with said main controller and said perfusion device and said controller being coupled to said power-supply-circuit and controls electrical power to said perfusion device.

- 22. An adapter pod as defined in claim 21 wherein said device connector has a first number of signal lines and wherein said common connector has a second number of signal lines different than said first number.
- 23. An adaptor pod for use in a medical perfusion system, wherein the medical perfusion system has a plurality of perfusion devices, including at least one blood pump, and a communication network that links each of the plurality of perfusion devices, the adaptor pod comprising:

a first connector for use in coupling the adaptor pod, through a data bus, to any one of a number of available connection points within the communication network;

a second connector for use in coupling the adaptor pod to the blood pump via a data line; and

means for controlling the transmission of a blood pump control signal from the adaptor pod to the blood pump over the data line.

- 24. The adaptor pod of claim 23, wherein the blood pump control signal defines a desired pump speed for the blood pump.
- 25. The adaptor pod of claim 23, wherein the blood pump control signal defines a mode of operation for the blood pump.
 - 26. The adaptor pod of claim 23, wherein the blood pump is a centrifugal pump.
 - 27. The adaptor pod of claim 23, wherein the blood pump is a roller pump.
- 28. The adaptor pod of claim 23 further comprising:
 means for processing an alarm signal received from the blood pump via the data line.
 - 29. The adaptor pod of claim 28 further comprising:

means for encoding an alarm message that identifies a type of alarm and an address associated with the blood pump; and

means for broadcasting the alarm message over the communication network.

30. An adaptor pod for use in a medical perfusion system, wherein the medical perfusion system has a plurality of perfusion devices, including at least one blood condition sensing device, and a communication network that links each of the plurality of perfusion devices, the adaptor pod comprising:

a first connector for use in coupling the adaptor pod, through a data bus, to any one of a number of available connection points within the communication network;

a second connector for use in coupling the adaptor pod to the blood parameter sensing device via a data line; and

means for receiving, over the data line, a blood parameter signal from the blood parameter sensing device.

- 31. The adaptor pod of claim 30 further comprising:

 means for reading a numeric value conveyed in the blood parameter signal,
 wherein the numeric value represents a corresponding blood parameter.
- 32. The adaptor pod of claim 31 further comprising:

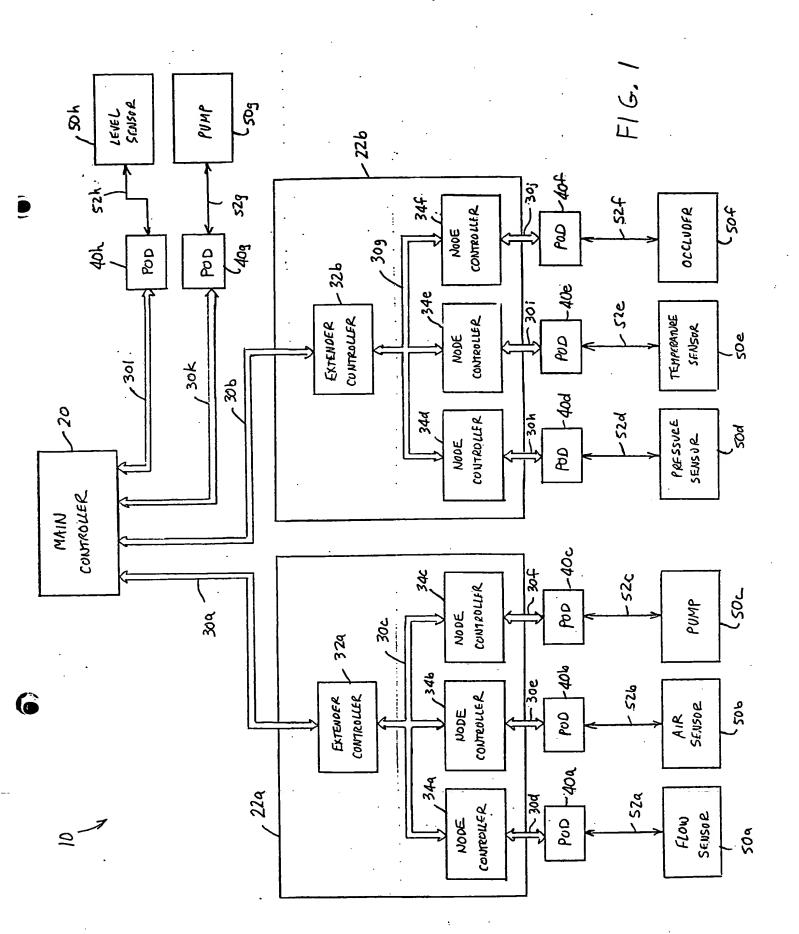
 means for encoding a message that identifies the numeric value and a
 network address associated with the blood parameter sensing device; and
 means for broadcasting the message over the communication network.
- 33. The adaptor pod of claim 32, wherein the numeric value represents blood flow.
- 34. The adaptor pod of claim 32, wherein the numeric value represents blood pressure:

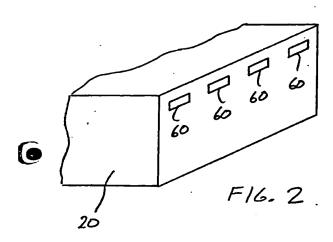
- 35. The adaptor pod of claim 32, wherein the numeric value represents blood temperature.
- 36. The adaptor pod of claim 32, wherein the numeric value represents a blood flow occlusion.
- 37. The adaptor pod of claim 32, wherein the numeric value represents the presence of an air embolus.
 - 38. The adaptor pod of claim 30 further comprising:

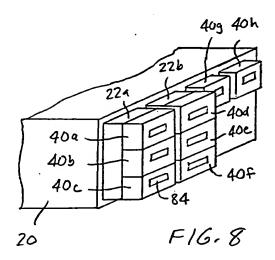
means for controlling the transmission of a blood parameter sensing device control signal from the adaptor pod to the blood parameter sensing device, wherein the blood parameter sensing device control signal defines a mode of operation for the blood parameter sensing device.

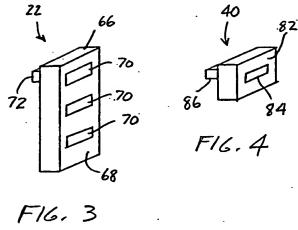
APPENDIX B

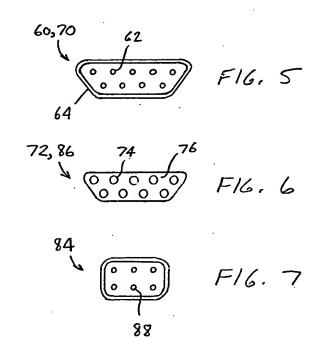
Figures 1-8, 12 and 17a-d

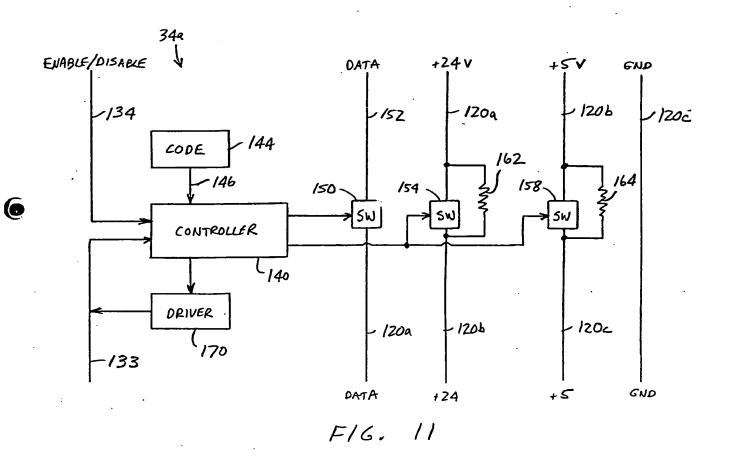


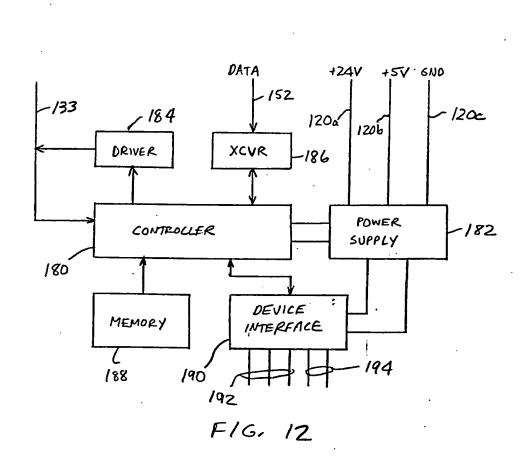












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